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(54) Detection apparatus and method for the same

Nachweisvorrichtung und Nachweismethode

Appareil de détection et méthode pour cela

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Description

BACKGROUND OF THE INVENTION

[0001] The present invention relates to a detection apparatus for detecting the presence of a detectable material in a sample. More specifically, the present invention relates to a detection apparatus for detecting the presence of a biological component in urine, blood, or the like. Additionally, the present invention relates to a method for the detection of a biological component in urine, blood, or the like.

[0002] Among conventional detection methods for detecting a biological component detectable material, there is an immunological detection method, which uses antibodies and antigens. This method, which provides high sensitivity and good specificity and ease of use, is used widely in the field of clinical testing. Various technologies have been recently proposed to perform testing using the immunological detection method without requiring any special techniques or training.

[0003] Of these, a group of measuring methods known as immunological chromatography has been proposed (Japanese laid-open patent publication number 9-178748) and is already being marketed to the general public. This method provides quick, easy, and accurate results.

[0004] In immunological chromatography, a marked reagent (staining indicator) using colored latex, colloidal gold, or the like, is fixed to a spreading layer. An unmarked reagent is fixed to a detection zone on the spreading layer. When the detectable material is present in the fluid sample, immunoreaction compounds are produced. The staining marker from this reaction is caught so that it can be visually observed. With the immunological chromatography method, the fluid sample can be simply applied to an application position. After a fixed period of time, the degree of coloration from the staining marker is observed at the detection zone.

[0005] With this method, the antigens or antibodies which have affinity for the detectable material must be prepared along with enzymes, fluorescent materials, luminescent materials, colored latex, colloidal gold, or the like, which serve as markers, that are chemically or physically bonded with marker antigens or marker antibodies depending on the application. However, the marking reaction involves a major problem. For example, to bond an enzyme to an antigen or antibody protein, a chemical procedure such as periodic acid oxidation can be performed (Enzyme Immunoassay, Igaku-Shoin, Tokyo, 1982). In such cases, irreversible deactivation of the antigen, antibody, or the enzyme takes place. Additionally, polymerization leading to reduction of activation or non-specific reaction can take place. As a result, the practical marker yield becomes very low.

[0006] Similarly, when physical (hydrophobic bonding) methods are used to bond colored latex to antigen or antibody proteins, the bonding to the colored latex takes place randomly so that the active sites of the antigen or antibodies are lost. This provides inadequate reactions so that excess antigens or antibodies must be used. Also, since absorption does not proceed 100%effectively, significant antigens or antibodies are wasted.

[0007] To overcome these problems, a method that uses bivalent reagents, as a crosslinking agent, has been developed (Enzyme Immunoassay, Igaku-Shoin, Tokyo, 1982). However, the operations involved are complex and require a high degree of skill. Furthermore, since the reaction itself is highly sensitive, slight changes in reaction conditions can greatly affect the properties of the marker. Thus, the bivalent reagent method of preparing markers is not considered very reproducible.

[0008] When using the conventional high-specificity marking method, the loss of activation of the markers or the antigens/antibodies or the like is unavoidable, and 100% marking cannot be achieved since the marking operation is itself a chemical reaction.

OBJECTS AND SUMMARY OF THE INVENTION

[0009] It is an object of the present invention to provide a detection method for minimizing reduced activation and antibody loss from the marking operation while providing measurement sensitivity that is at least equal to that of the conventional technology.

[0010] It is a further object of the present invention is to provide a detection apparatus that gives highly sensitive and inexpensive immunological detection without wasting valuable antibodies.

[0011] It is another object of the present invention to provide a detection method that gives highly sensitivity and inexpensive immunological detection without wasting valuable antibodies.

[0012] It is still a further object of the present invention to provide a high-sensitivity detection apparatus and method for detecting a detectable material that does not involve restrictions of reagent amounts.

[0013] According to an aspect of the present invention, there is provided a detection apparatus for detecting the presence of a detectable material in a sample comprising:

a fluid application section contacting said sample;

a reaction reagent section, having unmarked particles comprising an immunological reagent and marking particles comprising an immunological reagent movably contained therein, connected to said fluid application section such that said sample moves from said fluid application section to said reaction reagent section;
a porous reaction support section connected to said reaction reagent section such that said sample moves from said reaction reagent section to said porous reaction support section;
an immunological reaction product formed from biological bonding said detectable material with both said marking particles and said unmarked particles when said detectable material is present in said sample; and
a catching section in said porous section made from a material having a pore size smaller than a size of said reaction product, such that chromatographic movement of said marking particles not bonded to said unmarked particles is permitted through said catching section and chromatographic movement of said reaction product is restricted.

[0014] According to still another aspect of the present invention, there is provided a detection method for detecting the presence of a detectable material in a sample comprising:

contacting said sample with a fluid application section of a detection apparatus;
chromatographically moving said sample through said fluid application section, a reaction reagent section, and a porous reaction support section;
reacting said sample with unmarked particles comprising an immunological reagent and marking particles comprising an immunological reagent contained in said reaction reagent section to form an immunological reaction product, such that said detectable material biologically bonds with both said marking particles and said unmarked particles when said detectable material is present in said sample;
passing said sample, including any said reaction product present, through a catching section, having a pore size smaller than a size of said reaction product and larger than the diameter of the said marking particles; and analyzing presence of said marking particles at said catching section, whereby presence of said marking particles corresponds with presence of said detectable material.

[0015] A detection apparatus according to an embodiment of the present invention includes a fluid application section placed in contact with the sample fluid, a reaction reagent section connected to the fluid application section, and a porous carrier connected to the reaction reagent section. The reaction reagent section contains unmarked particles, which do not affect detection, and marking particles which, through biochemical reactions, bond with the unmarked particles through the detectable material. The particles and the marking elements are able to move through the porous carrier. A catching section, disposed at the detection zone, prevents chromatographical movement of the reaction product produced from the bonding of the unmarked particles and the marking particles with the detectable material. The catching section also allows chromatographic movement of marking particles not bonded with unmarked particles. The pore size of the catching section is smaller than the particle diameter of the reaction product and is larger than the particle diameter of the marking elements not bonded with particles.

[0016] With this structure, detection is completed simply by applying the fluid sample, waiting for a fixed period of time, and viewing the detection results at the detection zone.

[0017] The detection apparatus according to an embodiment of the present invention includes a fluid application section contacting a fluid sample. A reaction reagent section connects to the fluid application section. A porous carrier connects to the reaction reagent section. The reaction reagent section includes unmarked particles not affecting detection and marking particles. The marking particles bond, through a biochemical reaction, to the unmarked particles and the detectable material when the detectable material is present. The unmarked particles and the marking particles are movably contained in the porous carrier. A reaction product, produced from bonding between the unmarked particles and the marking particles to the detectable material, prevents chromatographic movement of the reaction product. A catching section is disposed at a detection zone to allow chromatographic movement of the marking particles not bonded to the unmarked particles. The pore size of the catching section is smaller than the particle diameter of the reaction product and is larger than the particle diameter of the marking particles not bonded to the unmarked particles.

[0018] With this structure, the unmarked reagent is not solidified in the porous carrier and is simply contained in the reaction reagent section. Thus, the amount of unmarked reagent is not restricted by the need to perform solidification. This allows a greater amount of unmarked reagent to be used compared to the conventional detection apparatus, providing improved detection sensitivity. Furthermore, since the unmarked reagent is not physically bound to the porous carrier, the unmarked reagent moves freely through the porous carrier and the free motion (collisions) between components efficiently promotes and speeds up the reaction compared to the conventional technology. This provides improved detection.

[0019] Also, if the detectable material is present, the marker bonds with the unmarked particles to form a reaction product, which is then caught at the catching section. Thus, there is no hindrance in obtaining the detection results.

[0020] Furthermore, the relationship between the pore size and the particle diameter of the unmarked particles, allows the reaction product produced by the bonding between the marking particles and the unmarked particles to stop and be caught at the catching section.

[0021] In the detection apparatus according to an embodiment of the present invention, the pore size of the catching section is smaller than the particle diameter of the unmarked particle.

[0022] With this structure, unbonded unmarked particles are also stopped at the catching section. This relationship between the diameters can be used when the detectable material has only one immunological reaction site of the same type. In this case, the reaction product and a single unmarked particle have roughly the same size, allowing the reaction product to stop at the catching section.

[0023] In the detection apparatus according to another embodiment of the present invention, the pore size of the catching section is larger than the particle diameter of the unmarked particle.

[0024] With this structure, unbonded unmarked particles pass through the catching section. The relationship between the diameters is suitable for when the detectable material has multiple immunological reaction sites of the same type. In such cases, the detectable material bonds with multiple particles so that the reaction product develops into an aggregate that is much larger than a single particle. Unless the particles are made smaller, the aggregate will become so large that the reaction products can get caught in the middle of the porous carrier without reaching the catching section. Therefore, the particle diameter should be made small to allow the reaction product to chromatographically move to the catching section.

[0025] The above, and other objects, features and advantages of the present invention will become apparent from the following description read in conjunction with the accompanying drawings, in which like reference numerals designate the same elements.

Figure 1(a) is a front-view drawing of a detection apparatus according to a first embodiment of the present invention;
Figure 1(b) is a side-view drawing the detection apparatus of Figure 5 (a);
Figure 2(a) is a front-view drawing of a detection apparatus according the first embodiment of the present invention (positive);
Figure 2(b) is a front-view drawing of the detection apparatus according to the first embodiment of the present invention (negative);
Figure 2(c) is a close-up view of the detection apparatus of Figure 6 (a);
Figure 3(a) is a front-view drawing of a detection apparatus according to the second embodiment of the present invention (positive);
Figure 3(b) is a front-view drawing of the detection apparatus according to the second embodiment of the present invention (negative);
Figure 3(c) is a close-up view of the detection apparatus of Figure 7(a);

[0026] Referring to Figures 1(a) and 1(b), in an embodiment of the present invention, the particle diameter of particles 13 is greater than the pore size of a catching section 16. This embodiment is useful for cases where a detectable material T (see Figure 2(c)) has just one immunological reaction site of the same type. Examples of detectable material T include hCG (human chorionic gonadotropin), LH (luteinizing hormone), FSH (follicle stimulating hormone), TSH (thyroid stimulating hormone), insulin, and CEA (carcinoembryonic antigen).

[0027] Referring to Figures 2(a), 2(b), and 2(c), a fluid application section 11, preferably formed from a filter paper, contacts the fluid sample by dripping the fluid sample onto the filter paper or by immersing the filter paper in the fluid sample. A reaction reagent section 12, continuous with fluid application section 11, contains particles 13 and marking elements 14.

[0028] Particles 13 do not affect the evaluation. If the evaluation is performed visually, particles 13 are white or transparent. When detectable material T is present, a biochemical (e.g., immunological) reaction takes place between marking elements 14 and particles 13, producing a reaction product 18.

A porous carrier 15 serves as a reaction support body. The pore size of porous carrier 15 is set to be larger than the particle diameters of particles 13 and the size of reaction products 18. Marking elements 14, particles 13, and reaction product 18 are able to freely move chromatically through porous carrier 15.

[0029] A catching section 16 is disposed at an intermediate position (detection zone) in porous carrier 15. The pore size of catching section 16 is set to be smaller than the particle diameter of particles 13 and the size of reaction product 18, but larger than the particle diameter of marking element 14. Catching section 16 is sandwiched between and linked in series with two porous carriers 15.

[0030] If necessary, a fluid absorption section 17, formed from filter paper or the like, is connected to porous carrier 15 to allow the fluid sample to move chromatically. In this second embodiment, the spreading layer is formed from fluid collection section 13, porous carrier 15, and fluid absorption section 17.

[0031] When fluid application section 11 contacts the fluid sample, the fluid sample begins moving in the direction

indicated by an arrow N. Then, when the fluid sample reaches reaction reagent 12, particles 13 and marking elements 14 in reaction reagent section 12 begin moving together with the fluid sample. Since particles 13 are not fixed to porous carrier 15 they can move freely.

[0032] If the detectable material T is present in the fluid sample, reaction product 18 is produced in porous carrier 15, as shown in Fig 2(c). The bonding between particle 13 and detectable material T as well as the bonding between detectable material T and marking elements 14 result in a bond between marking elements 14 and particle 13 via detectable material T. Reaction product 18 from this embodiment embodiment has a size that is roughly similar to that of particles 13. If the detectable material T is not present, reaction product 18, as shown in Figure 2(c), would not be formed. Instead, marking elements 14 and particles 13 would move separately as shown in Figure 2(b).

[0033] When catching section 16 is reached, particles 13 and reaction product 18 are caught by catching section 16 and cannot proceed further. Marking element 14, however, is able to pass through catching section 16 to reach fluid absorption section 17.

[0034] If the detectable material T is present and the results are positive, reaction products 18 are kept at catching section 16. Marking elements 14, being a part of reaction products 18, stay at catching section 16 as well. Conversely, if no detectable material T is present and the results are negative, only particles 13 are kept at catching section 16. Marking elements 14 pass through catching section 16 without stopping at catching section 16.

[0035] As a result, a visual inspection or sensing can be performed on catching section 16 to determine if the results are positive or negative.

[0036] In the description above, catching section 16 has a smaller pore size and is linked in series with porous carrier 15. However, the present invention is not restricted to this structure. For example, it is also possible to reduce the effective pore size of porous carrier 15 itself to use it as a substitute for catching section 16. This can be achieved by applying heat treatment or chemical treatment on porous carrier 15, or by applying chemical or physical processing in order to embed particles, such as white latex, in porous carrier 15.

[0037] In this embodiment, as described above, detection is performed without having to fix marking elements 14 onto porous carrier 15. As a result, the conventional technology's restrictions on the amount of particles and marking elements that can be used are eliminated while the reaction volume itself can be greatly increased, thus improving the sensitivity of detection.

[0038] Also, since the concentrations for particles 13 and marking elements 14 can be adjusted freely, production control is made easier. In the production process used for the conventional detection apparatus, it is necessary to fix the making elements and perform special steps in order to improve the reliability of the flow through the porous carrier. The present invention reduces the burden of these steps.

[0039] In example 1 the detectable material is the pregnancy marker hCG. Example 1 is performed according to the embodiment described above.

[0040] Anti-beta hCG antibody was bonded to 1 micron white latex, serving as particle 13. Anti-hCG antibody was bonded to 0.3 micron colored latex or 0.02 micron colloidal gold. Bonding was performed using standard methods.

[0041] The reaction reagent was formed in the following manner. For the particles, 4.8 microliters were used per test at 0.1% concentration. When colored latex was used for the marking element, 3.6 microliters were used per test at 0.3% concentration. When colloidal gold was used for the marking element, 4.8 microliters were used per test at a concentration that provides absorbency of 5.0 for light at 520 nm. The reaction reagents were mixed and applied to an intermediate portion of a fiberglass pad, which served as the porous carrier. For the fluid application section, filter paper was connected to the fiberglass pad. A nitrocellulose membrane (trade name SCHF from Millipore Corp.) was used as the catching section. These were combined to form the detection apparatus.

[0042] Eighty microliters, each of a positive sample containing hCG and a negative sample not containing hCG, were absorbed into the fluid application sections. After five minutes, the coloring at the catching sections was observed. For the sample containing hCG, coloring formed by the marking element appeared at the catching section in a range of 50 mIU/ml - 1,000,000 mIU/ml. For the sample not containing hCG, no coloring was observed and a negative evaluation was made.

[0043] Referring to Figures 3(a), 3(b), and 3(c), in a second embodiment of the present invention, the particle diameter of a particle 19 is less than the pore size of catching section 16. In this embodiment, a detectable material S has multiple immunological reaction sites of the same type. Examples of the detectable material S include HBsAg (hepatitis B surface antigen), CRP (C-reactive protein), hemoglobin, and various antibodies (antibody detect).

[0044] The second embodiment differs from the first embodiment in the relationship between particle diameter and pore size as well as the properties of detectable material S. When detectable material S has multiple immunological reaction sites of the same type, a single detection material S can bond with multiple particles 19. In addition, particles 19 can bond with other detectable materials S. When this type of chained bonding takes place, a reaction product 20 becomes an aggregate of multiple particles 19. The size of this aggregate is much greater than the size of single particle 13. If the size of particle 13 increases, the size of reaction product 20 will increase roughly proportionally. This can result in reaction product 20 stopping in the middle of porous carrier 15 so that reaction product 20 cannot move

chromatographically as shown by arrow N. This makes it impossible to determine a positive or negative evaluation in catching section 16.

Therefore, the relation between particle diameter and pore size is such that the particle diameter of particles 19 is less than the pore size of catching section 16. In this configuration, reaction products 20, which have grown large, will be stopped at catching section 16. When no reaction products 20 are formed, however, particles 19 and marking elements 14 will pass through catching section 16 to reach fluid absorption section 17. Otherwise, the positive and negative evaluations as well as the operations and advantages are similar to those of the first embodiment.

[0045] In example 2 the detectable material is the hepatitis B surface antigen HBsAg. Example 2 is performed according to the second embodiment as described above.

[0046] Anti-HBsAg antibodies were bonded to 0.3 micron white latex, serving as particles 19. An anti-HBsAg antibody having a different epitope was bonded to colloidal gold, serving as the marking element. The bonding was performed using standard methods.

The reaction reagent was formed in the following manner. For the particles, 60 microliters was used per test at a concentration of 0.01%. This was mixed with 60 microliters of marking element per test at a concentration that provided absorbency of 0.6 for 520 nm light. This was applied to an intermediate section of a fiberglass pad, which served as the porous carrier. For the fluid application section, filter paper was connected to the glass pad. A nitrocellulose membrane (trade name SCHF from Millipoa Corp.) was used as the catching section. These were combined to form the detection apparatus.

[0047] Eighty microliters, each of a positive sample containing HBsAg and a negative sample not containing HBsAg, were absorbed into the fluid application sections. After fifteen minutes, the coloring at the catching sections were observed. For the sample containing HBsAg, coloring formed by the marking element appeared at the catching section in a range of 10 micrograms/ml - 25 micrograms/ml. For the sample not containing HBsAg, no coloring was observed and a negative evaluation was made.

Table 1

	Desirable size	Example	More desirable size
Particles	0.2 - 5 Fm	1	approx. 1 Fm white latex
		2	approx 0.3- 0.7 Fm white latex
Marking elements	0.02 - 0.6 Fm	1	approx. 0.02 Fm colloidal gold
			approx 0.3 Fm colored latex
		2	approx. 0.02 Fm colloidal gold
Porous carrier	5 - 200 Fm	1	approx. 100 Fm fiberglass pad
		2	approx. 100 Fm fiberglass pad
Catcher	0.3 - 20 Fm	1	nitrocellulose membrane
		2	nitrocellulose membrane

[0048] Table 1 summarizes the materials used in Examples 1 and 2. In Example 1, according to the first embodiment of the present invention, the particle diameter is greater than the pore size, and the detectable material is hCG. In Example 2, according to the second embodiment of the present invention, the particle diameter is less than the pore size, and the detectable material is HBsAg.

[0049] According to the first technology of the present invention, an immunological complex is formed with the detectable material, after which a marking reaction is generated. Since detection is performed without using marking antibodies, precious antibodies need not be wasted. Furthermore, stearic hindrance and kinetic degradation due to the marking reaction is prevented, allowing the antigen-antibody reaction to proceed smoothly. Detection time is reduced and high sensitivity is provided.

[0050] Also, since marking is performed using immunological methods, markers such as watersoluble dies and the like can be used in addition to the conventional enzymes, colloidal gold, colored latex, and the like. This makes it possible to perform detection on materials that have been conventionally difficult to mark due to, for example, deactivation.

[0051] According to the second technology of the present invention, the concentration of the particles and marking elements is increased, the motion of the marking elements and particles is made more smooth, and detection sensitivity is increased. Also, the production process is simplified.

[0052] Having described preferred embodiments of the invention with reference to the accompanying drawings, it is

to be understood that the invention is not limited to those precise embodiments, and that various changes and modifications may be effected therein by one skilled in the art.

Claims

1. A detection apparatus for detecting the presence of a detectable material in a sample comprising:

   a fluid application section contacting said sample;
   a reaction reagent section, having unmarked particles comprising an immunological reagent and marking particles comprising an immunological reagent movably contained therein, connected to said fluid application section such that said sample moves from said fluid application section to said reaction reagent section;
   a porous reaction support section connected to said reaction reagent section such that said sample moves from said reaction reagent section to said porous reaction support section;
   an immunological reaction product formed from biological bonding said detectable material with both said marking particles and said unmarked particles when said detectable material is present in said sample; and
   a catching section in said porous section made from a material having a pore size smaller than a size of said reaction product, such that chromatographic movement of said marking particles not bonded to said unmarked particles is permitted through said catching section and chromatographic movement of said reaction product is restricted.

2. A detection apparatus for detecting the presence of a detectable material in a sample according to Claim 1, wherein said pore size of said catching section is smaller than the particle diameter of said unmarked particles.

3. A detection apparatus for detecting the presence of a detectable material in a sample according to Claim 1 or Claim 2, wherein said detectable material is selected from at least one of human chorionic gonadotropin, luteinizing hormone, follicle stimulating hormone, thyroid stimulating hormone, insulin, and carcinoembryonic antigen.

4. A detection apparatus for detecting the presence of a detectable material in a sample according to Claim 5, wherein said pore size of said material of said catching section is larger than the particle diameter of the said unmarked particles.

5. A detection apparatus for detecting the presence of a detectable material in a sample according to Claim 4, wherein said detectable material is selected from at least one of hepatitis B surface antigen, C-reactive protein, and hemoglobin.

6. A detection method for detecting the presence of a detectable material in a sample comprising:

   contacting said sample with a fluid application section of a detection apparatus;
   chromatographically moving said sample through said fluid application section, a reaction reagent section, and a porous reaction support section;
   reacting said sample with unmarked particles comprising an immunological reagent and marking particles comprising an immunological reagent contained in said reaction reagent section to form an immunological reaction product, such that said detectable material biologically bonds with both said marking particles and said unmarked particles when said detectable material is present in said sample;
   passing said sample, including any said reaction product present, through a catching section, having a pore size smaller than a size of said reaction product and larger than the diameter of the said marking particles; and
   analyzing presence of said marking particles at said catching section, whereby presence of said marking particles corresponds with presence of said detectable material.

Patentansprüche

1. Nachweisvorrichtung zum Nachweisen des Vorhandenseins eines nachweisbaren Materials in einer Probe mit einem Flüssigkeitsaufbringungsabschnitt, der mit der Probe in Kontakt steht,
   einem Reaktionsreagensabschnitt, der unmarkierte Teilchen mit einem immunologischen Reagens und Markierungsteilchen mit einem immunologischen Reagens aufweist, die bewegbar darin enthalten sind, und der mit dem Flüssigkeitsaufbringungsabschnitt derart verbunden ist, dass sich die Probe von dem Flüssigkeitsaufbringungs-

abschnitt zu dem Reaktionsreagensabschnitt bewegt,
einem porösen Reaktionsträgerabschnitt, der mit dem Reaktionsreagensabschnitt derart verbunden ist, dass sich die Probe von dem Reaktionsreagensabschnitt zu dem porösen Reaktionsträgerabschnitt bewegt,
einem immunologischen Reaktionsprodukt, das durch biologisches Binden des nachweisbaren Materials sowohl an die Markierungsteilchen als auch an die unmarkierten Teilchen gebildet wird, wenn das nachweisbare Material in der Probe vorhanden ist, und
einem Einfangabschnitt in dem porösen Abschnitt, der aus einem Material, das eine Porengröße kleiner als die Größe des Reaktionsproduktes besitzt, derart gemacht ist, dass die chromatographische Bewegung der Markierungsteilchen, die nicht an die unmarkierten Teilchen gebunden sind, durch den Einfangabschnitt zugelassen ist und die chromatographische Bewegung des Reaktionsproduktes beschränkt ist.

2. Nachweisvorrichtung zum Nachweisen des Vorhandenseins eines nachweisbaren Materials in einer Probe nach Anspruch 1, bei der die Porengröße des Einfangabschnitts kleiner ist als der Teilchendurchmesser der unmarkierten Teilchen.

3. Nachweisvorrichtung zum Nachweisen des Vorhandenseins eines nachweisbaren Materials in einer Probe nach Anspruch 1 oder Anspruch 2, bei der das nachweisbare Material ausgewählt ist aus mindestens einem von menschlichem Choriongonadotropin, Luteinisierendem Hormon, Follikelstimulierendem Hormon, Thyroidstimulierendem Hormon, Insulin und karzinoembryonales Antigen.

4. Nachweisvorrichtung zum Nachweisen des Vorhandenseins eines nachweisbaren Materials in einer Probe nach Anspruch 5, bei der die Porengröße des Materials des Einfangabschnitts größer ist als der Teilchendurchmesser der unmarkierten Teilchen.

5. Nachweisvorrichtung zum Nachweisen des Vorhandenseins eines nachweisbaren Materials in einer Probe nach Anspruch 4, bei der das nachweisbare Material ausgewählt ist aus mindestens einem von Hepatitis B-Oberflächenantigen, C-reaktivem Protein und Hämoglobin.

6. Nachweisverfahren zum Nachweisen des Vorhandenseins eines nachweisbaren Materials in einer Probe mit
in Kontakt Bringen der Probe mit einem Flüssigkeitsaufbringungsabschnitt einer Nachweisvorrichtung, chromatographisches Bewegen der Probe durch den Flüssigkeitsaufbringungsabschnitt, einen Reaktionsreagensabschnitt und einen porösen Reaktionsträgerabschnitt,
zur Reaktion Bringen der Probe mit unmarkierten Teilchen mit einem immunologischen Reagens und Markierungsteilchen mit einem immunologischen Reagens, die in dem Reaktionsreagensabschnitt enthalten sind, um ein immunologisches Reaktionsprodukt derart zu bilden, dass das nachweisbare Material biologisch an die Markierungsteilchen und die unmarkierten Teilchen bindet, wenn das nachweisbare Material in der Probe vorhanden ist,
Leiten der Probe einschließlich jedes vorhandenen Reaktionsproduktes durch einen Einfangabschnitt mit einer Porengröße, die kleiner ist als die Größe des Reaktionsprodukts und größer ist als der Durchmesser der Markierungsteilchen, und
Analysieren des Vorhandenseins der Markierungsteilchen in dem Einfangabschnitt, wobei das Vorhandensein der Markierungsteilchen mit dem Vorhandensein des nachweisbaren Materials übereinstimmt.

Revendications

1. Appareil de détection de la présence d'une matière détectable dans un échantillon comprenant :

une section d'application de fluide venant en contact avec ledit échantillon ;
une section de réactif, comportant des particules non marquées constituées par un réactif immunologique et des particules de marquage constituées par un réactif immunologique et aptes à se déplacer l'intérieur de ladite section, reliée à ladite section d'application de fluide de sorte que ledit échantillon se déplace de ladite section d'application de fluide vers ladite section de réactif ;
une section poreuse de support de réaction reliée à ladite section de réactif de sorte que ledit échantillon se déplace de ladite section de réactif vers ladite section poreuse de support de réaction ;
un produit de réaction immunologique formé à partir d'une liaison biologique de ladite matière détectable avec à la fois lesdites particules de marquage et lesdites particules non marquées lorsque ladite matière détectable est présente dans ledit échantillon ; et
une section de captage dans ladite section poreuse réalisée à partir d'une matière ayant une taille de pore

inférieure à la taille dudit produit de réaction, de sorte que le mouvement chromatographique desdites particules de marquage non liées auxdites particules non marquées est permis à travers ladite section de captage et le mouvement chromatographique dudit produit de réaction est limité.

2. Appareil de détection de la présence d'une matière détectable dans un échantillon selon la revendication 1, dans lequel ladite taille de pore de ladite section de captage est inférieure au diamètre de particule desdites particules non marquées.

3. Appareil de détection de la présence d'une matière détectable dans un échantillon selon la revendication 1 ou la revendication 2, dans lequel ladite matière détectable est sélectionnée à partir d'au moins un élément choisi parmi la gonadotropine chorionique humaine, l'hormone lutéinisante, l'hormone folliculo-stimulante, l'hormone thyroïdo-stimulante, et l'antigène carcino-embryonnaire.

4. Appareil de détection de la présence d'une matière détectable dans un échantillon selon la revendication 5, dans lequel ladite taille de pore de ladite matière de ladite section de captage est supérieure au diamètre desdites particules non marquées.

5. Appareil de détection de la présence d'une matière détectable dans un échantillon selon la revendication 4, dans lequel ladite matière détectable est au moins un élément choisi parmi l'antigène de surface de l'hépatite B, la protéine C-réactive, et l'hémoglobine.

6. Procédé de détection de la présence d'une matière détectable dans un échantillon comprenant :

la mise en contact dudit échantillon avec une section d'application de fluide d'un appareil de détection ;
le déplacement chromatographique dudit échantillon à travers ladite section d'application de fluide, une section de réactif, et une section poreuse de support de réaction ;
la réaction dudit échantillon avec des particules non marquées constituées par un réactif immunologique et des particules de marquage constituées par un réactif immunologique contenu dans ladite section de réactif pour former un produit de réaction immunologique, de sorte que ladite matière détectable se lie du point de vue biologique à la fois auxdites particules de marquage et auxdites particules non marquées lorsque ladite matière détectable est présente dans ledit échantillon ;
le passage dudit échantillon, y compris tout produit de réaction présent, à travers une section de captage, de dimension de pore inférieure à la dimension dudit produit de réaction et supérieure au diamètre desdites particules de marquage ; et
l'analyse de la présence desdites particules de marquage au niveau de ladite section de captage, de sorte que la présence desdites particules de marquage correspond à la présence de ladite matière détectable.

Fig. 1 (a)

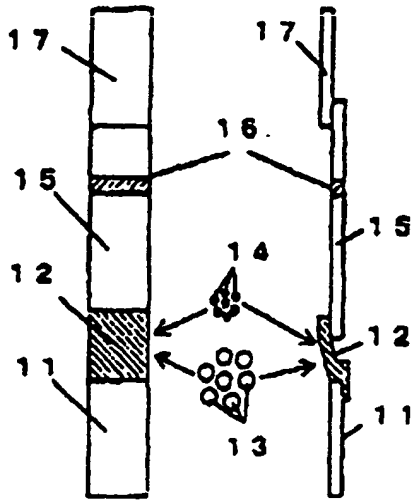

Fig. 1 (b)

Fig. 2 (a)

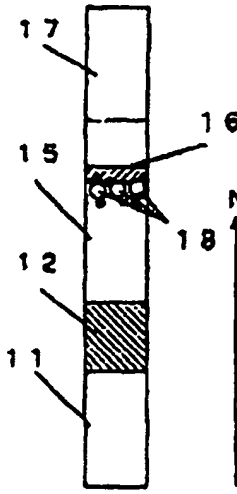

Fig. 2 (b)

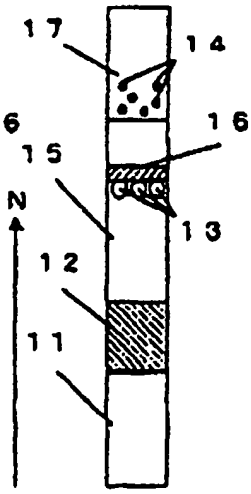

Fig. 2 (c)

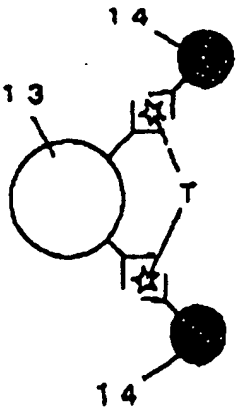

Fig. 3 (a)

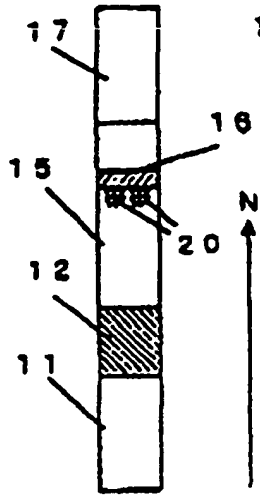

Fig. 3 (b)

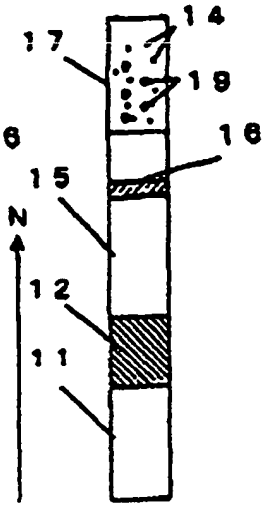

Fig. 3 (c)